

## REMARKS

This Response Under 37 CFR §1.116 is respectfully submitted in response to the Office Action rendered April 23, 2007. Applicants gratefully acknowledge the withdrawal of all rejections set forth in the October 23, 2006 Final Rejection except those reiterated in the Office Action of April 23, 2007.

The Office Action rendered April 23, 2007 rejected claims 75-84 under 35 U.S.C. 102 as being anticipated by JP 4081483442. Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

The Office Action gives, as basis for the rejection, that:

JP '442 teaches a water extract of soybeans used to treat eczema. Whole soybeans are ground and water is added and then the extract is filtered. The ground matter is heated but to a temperature which could read on 5°C...it is clear that the soybeans were ground which would crush the soybean and that the soybean was heated anywhere from 5-100°C. Thus, it could have been heated to only 5°C which would have not denatured the protein." [Office Action, p. 3]

Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

Applicants have again reviewed the entire JP8143442 publication and have the following comments. As noted previously, JP8143442 relates to an "immersed solution", i.e., water in which soybeans have been immersed for five minutes to 20 hours at a temperature from 5 to 100°C and from which the soybeans have been removed. Applicants acknowledge that the '442 publication indicates that there are different soaking times and temperatures stated, such as the following:

Therefore, as preferred conditions, soaking is carried out at 20 to 30°C for 8 to 20 hours, at 40 to 55°C for 1 to 6 hours or 70 to 90°C for 5 to 30 minutes. After the soaking, separation into soybeans and soaked liquid is carried out, and this soaked liquid is used as a raw material...['442 Publication, pp. 6-7]

Notwithstanding, the '442 publication clearly suggests that proteins should not be included in the resulting soaking water:

In the case where a soaked liquid of defatted soybeans is used as a raw material, defatted soybeans are soaked at 20 to 30°C for 2 to 3 hours, or at 40 to 55°C for 0.5 to 1 hour. In this case, in order *to prevent the elution of proteins as much as possible*, the pH of the water for soaking during soaking is preferably adjusted at

4 to 5 with an organic acid or an inorganic acid. (emphasis added) [‘442 publication, p. 7]

Thus, the ‘442 publication clearly indicates that proteins (including, for example, the STI protein), are undesirable in the elute product described and the authors seek to reduce substantially or eliminate their presence in the elute.

Applicants further respectfully acknowledge that JP ‘442 mentions treatment of both whole soybeans and of crushed soybeans. However, the treatment regimen for whole soybeans and that for crushed soybeans differ in significant ways. For example, JP ‘442 at p. 2 of the translation refers to making an external preparation blended with a water extract liquid of soybeans. This liquid is derived from soaking for five minutes whole soybeans which are *not* crushed—it is unlikely that STI can diffuse from the soybeans in such a short period of time. Furthermore, even when dehulled soybeans are utilized, only the outer shell of the soybeans is removed, leaving the beans in whole form. Thus, little if any STI will diffuse. The case in which defatted soybeans are utilized is discussed above.

Thus, the ‘442 publication neither discloses nor suggests the methods or compositions of applicants’ invention.

The Office Action of April 23, 2007 also rejected claims 75-84 under 35 U.S.C. 102(a) as being anticipated by JP 410226642 (abstract). The basis for this rejection was that:

JP ‘642 teaches an extract of soybeans used to treat psoriasis. The extract can be applied in an ointment form...Applicant argues that the genistein has to be denatured in order to be ingested by humans but upon closer inspection of JP ‘642 it is clear that the extract is applied topically, i.e., as an ointment. Thus, it does not have to be ingested by humans as applicants argue. [Office Action, p. 4]

Applicants respectfully submit that neither of the cited references teaches or suggests the soybean extract of applicants’ claimed compositions and methods that has active trypsin inhibitory activity. Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

In general, applicants respectfully note that the reference to a “soy extract” in a cited patent or publication does not necessarily pinpoint the particular extracts that are useful in the compositions and methods of applicants’ invention. There are a variety of extracts obtained from the soy plant by different means, which do not necessarily suggest or disclose

the soy extracts containing trypsin inhibitory activity of the compositions and methods of applicants' invention. The '642 publication clearly refers to "pure genistein", which is an extract of soybeans that does not contain soy trypsin inhibitors. Genistein is generally extracted from soybeans using organic solvents, which should denature STI. For example, U.S. Patent No. 5,141,746 describes a process for extracting genistin malonate and daidzin malonate from soybeans using a "water-immiscible organic solvent." [See U.S. Patent No. 5,141,746, col. 1, l. 52-62, attached hereto] Thus, the '642 publication neither suggests nor describes the compositions or methods of applicants' invention.

In view of the insufficiency of the cited references to teach or suggest the compositions or methods of their invention, Applicants respectfully request reconsideration of the rejection under 35 U.S.C. 102 (a or b).

In view of the foregoing, applicants respectfully request reconsideration of the rejections set forth in the Final Rejection of April 23, 2007. An early allowance is earnestly solicited.

Respectfully submitted,

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Dated: September 21, 2007